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| 09/846,347      | 04/30/2001  | George Jackowski     | 2132.032            | 3155             |

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EXAMINER

CHEU, CHANGHWA J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1641

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/846,347

**Applicant(s)**

JACKOWSKI ET AL.

**Examiner**

Jacob Cheu

**Art Unit**

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 9/10/2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 36-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. Applicant's amendment filed on September 10, 2003 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 2-35 are cancelled.
2. Claims 36-43 are added to the instant application.

### ***Election/Restrictions***

2. In view of the newly added claims, the following restriction is set forth below

- I. Claim 1, drawn to biopolymer markers, classified in class 436, subclass 512.
- II. Claim 36-40, drawn to a method for diagnosing congestive heart failure, classified in class 436, subclass 86.
- III. Claim 41-43, drawn to a diagnostic kit, classified in class 422, subclass 119.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products from invention I, can be practiced with another materially different process other than invention II, such as isolation and separation of the specific analytes.

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4. Similarly, inventions III and II are also related as product and process of use. Likewise, invention III can be practiced by materially different process other than inventions II, such as isolation and separation.

5. Inventions I and III are patentably distinct and unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case invention I is directed to biopolymers consisting of specific polypeptides, whereas invention III is directed to polyclonal antibodies produced against the polypeptide markers. Both polypeptides and antibodies are patentably distinct in terms of structure and functions. Therefore, inventions I and III are distinct and unrelated inventions.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one group is not required for the other, therefore restriction for examination purposes as indicated is proper.

7. Newly submitted claims 36-43 are directed to an inventions that are independent or distinct from the invention originally claimed for reasons mentioned above.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 36-43 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

8. Currently, claim 1 is under examination.

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***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 1 is rejected under 35 U.S.C. 102 (a) as being anticipated by Bar-Or et al. (A) (WO200125265)

Bar-Or et al. reference is an invention relates to a metal binding peptides that prevent damage by reactive oxygen. Bar-Or et al. teach a sequence of polypeptides containing the instant SEQ ID No. 1 as a reactive species inhibitory peptide. (Example 10, page 43) It has been held that a recitation of *the intended use* of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Accordingly, the recited intended use, i.e. congestive heart failure detection, in the instant product claim is not given any patentable weight for examination.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1 is rejected under 35 U.S.C. 102 (b) as being anticipated by Bar-Or et al.(B)(WO000020840)

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With respect to claim 1, Bar-Or et al. teach a rapid method for the detection of heart ischemic states and kits for use in such method. Bar-Or et al. teach a sequence of polypeptides contains of the instant SEQ ID. No.1 as the measurement of an ischemic event. (See Example 32, page 60)

***Response to Applicant's Arguments***

***Rejection under 35 U.S.C. 102 (a) and (b)***

14. Applicant argues that the recited polypeptides possessing a patentably different use, i.e. as a marker to detect congestive heart failure in patients, rather than inhibition of production of reactive oxygen species or detection of cardiovascular ischemic states as taught in the Bar-Or et al. reference (WO 01/25265; WO 00/20840). Accordingly, prior arts cited by the examiner fail to teach every feature of the claim (see MPEP 2131), therefore anticipation rejections under 35 U.S.C § 102 should be withdrawn. Applicant's request is considered but appears not persuasive. As it has been held that a recitation of *the intended use* of the claimed product would not be given patentable weight in examination unless the claimed invention results in a structural difference compared to the prior art. Supra.

***Rejection under 35 U.S.C. 103 (a)***

15. Applicant has cancelled claims 2-35, therefore, the rejection under 35 U.S.C. 103 (a) is now moot.

***Request for rejoining newly added claims for examination***

9. Applicant asserts that the newly added claims 36-43 are directed to a non-elected claims, and requests for rejoinder for reexamination if amended claim 1 is allowable under *Ochiai* decision. Applicant's request is considered but appears not persuasive because there is no

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allowable subject matter indicated in this Office Action. Accordingly, newly added claims 36-43 are withdrawn from consideration.

**Conclusion**

10. No claim is allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 9:00-5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-746-9434.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu  
Examiner  
Art Unit 1641



December 12, 2003, 2003

  
LONG LE  
SUPERVISOR  
TECHNICAL  
12/15/03

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